

**REMARKS UNDER 37 CFR § 1.111**

**Formal Matters**

Claims 1-4 and 6-15 are pending after entry of the amendments set forth herein.

Claims 1-4 and 6-8 were examined. Claims 1-4 and 6-8 were rejected. No claims were allowed.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

**Rejection of claims under 35 U.S.C. § 101**

The claims remain rejected under 35 U.S.C. § 101, because the claimed invention assertedly lacks patentable utility. The Applicants respectfully traverse this rejection.

The claims are directed to polynucleotides having at least 50 contiguous nucleotides of SEQ ID NO:222. Accordingly, every single species of polynucleotide claimed has at least 50 contiguous nucleotides of SEQ ID NO:222.

The Applicants respectfully submit that such polynucleotides may be used, without any further modification, as probes for detecting cancerous cells, or as starting materials for making such probes. The fact that the claimed polynucleotides may have other sequences in addition to 50 contiguous nucleotides of SEQ ID NO:222 (e.g., polynucleotides *comprising* 50 contiguous nucleotides of SEQ ID NO:222) does not effect this utility. The polynucleotides have patentable utility by virtue of the fact that they all contain at least 50 contiguous nucleotides of SEQ ID NO:222.

The Office, on page of the Office Action, indicates that the data set forth in Table 5 of the specification is unclear. The Office states “It would seem like SEQ ID NO:222 is actually not discriminatory between normal colon tissue and colon tumor tissue – unless the sample is metastatic.” The Applicants respectfully submit that by making this statement, the Office is acknowledging that the data set forth in Table 5 shows that SEQ ID NO:222 may be used to detect cancer cells: metastatic colon cancer cells.

Accordingly, one example of a utility for the claimed polynucleotides is a diagnostic for detecting metastatic colon cancer cells. This is already acknowledged by the Office.

In summary, by virtue of the fact that all of the claimed polynucleotides contain at least 50 contiguous nucleotides of SEQ ID NO:222, the Applicants respectfully submit that one utility of the claimed polynucleotides is to detect metastatic colon cancer cells.

Since detecting metastatic colon cancer cells is a credible, specific and substantial utility for the claimed invention, the Applicants respectfully request withdrawal of this rejection without any further discussion.

**Rejection of claims under 35 U.S.C. § 112, first paragraph (enablement)**

The claims remain rejected under 35 U.S.C. § 112, first paragraph, because one of skill in the art would assertedly not know how to use the claimed invention. The Applicants respectfully traverse this rejection.

The Applicants respectfully submit that this rejection has been addressed by the reasoning set forth in the previous section: one of skill in the art would use the claimed invention for detecting metastatic colon cancer cells, for example.

In view of the foregoing discussion, the Applicants respectfully request withdrawal of this rejection.

**Rejection of claims under 35 U.S.C. § 112, first paragraph (written description)**

The claims remain rejected under 35 U.S.C. § 112, first paragraph, as encompassing subject matter that is assertedly inadequately described by the specification. The Applicants respectfully traverse this rejection.

The Office firstly states that the Applicants previous arguments regarding the case-law cited in the last Office Action was not persuasive because the arguments were not specifically related to the fact pattern of the present application.

The Applicants respectfully submit that this is not so. The sections entitled: “*The Facts of the Cited Cases are Distinct from those of the Instant Application*” and “*The Applicants of the Instant Application have Provided Nucleotide Sequences that Define the Claimed Polynucleotides*”, as found on pages 13 and 14 of the previous response, specifically discusses the cited caselaw and the instant claims in detail. For example, the second paragraph on page 14 states:

“This sequence recited in the claims provides the claimed invention with a critical defining feature – one that was said to be lacking in the claims considered and rejected in each of *Amgen*, *Fiers*, *Lilly*, and *Fiddes*. The sequence recited in the claims defines the claimed polynucleotide “so as to distinguish it from other materials.”<sup>1</sup> The recited sequence also provides “a structural or equivalent definition” of the claimed polynucleotide.<sup>2</sup> Moreover, the sequence recited in the claims provides “a recitation of structural features common to the members of the [claimed] genus.”<sup>3</sup> Thus, it is much more than a mere wish to obtain a composition – it defines the composition.”

The Applicants respectfully re-iterate their previous arguments that the caselaw cited in rejecting the claims is inapposite. In fact, if properly considered, the instant claims actually *meet* the requirements for written description set forth in the cited cases.

The remainder of the Office Action states that the claimed polynucleotides read upon other DNA sequences (e.g., intact genomic material or chromosomal material having introns, promoters, enhancers, terminators, etc), variations, fusions, deletions, and insertions etc., of SEQ ID NO:222 that are not specifically described in the specification, and, as such are rejectable as being inadequately described. In other words, the Office rejects the instant claims because they read on polynucleotide species that are not specifically described in the instant specification.

However, the fact that a claim may *read on* a species that is not specifically described in the claim is not a barrier to patentability of the claim. It is well established that even in an “unpredictable art,” applicants “are *not* required to disclose *every* species encompassed by their claims . . . .”<sup>4</sup> Thus, features that apply to only some species within a generic claim – but not to *all* species encompassed by the claim – need not be described to satisfy the written description requirement. Otherwise, to claim a genus, every species within a genus would have to be explicitly described. That is not the law.<sup>5</sup>

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<sup>1</sup> *Amgen*, 927 F.2d at 1206.

<sup>2</sup> *Fiers*, 984 F.2d at 1169. *See also Fiddes*, 30 USPQ2d at 1482-83.

<sup>3</sup> *Lilly*, 119 F.3d at 1568-69.

<sup>4</sup> *In re Angstadt*, 537 F.2d 498, 502-03, 190 U.S.P.Q. (BNA) 214, 218, (C.C.P.A. 1976).

<sup>5</sup> *See Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1531, 20 U.S.P.Q.2d (BNA) 1300, 1302 (Fed. Cir. 1991) (“Unclaimed subject matter is not subject to the disclosure requirements of § 112; the reasons are pragmatic: the disclosure would be boundless, and the pitfalls endless.”). *See also Phillips Petroleum v. U.S. Steel Corp.*, 673 F. Supp. 1278, 1292, 6 U.S.P.Q.2d (BNA) 1065, 1074 (D. Del. 1987) (“The applicant is not required to include in his application support for matters not set forth in the claim.”), *aff’d* 865 F.2d 1247, 9 U.S.P.Q.2d (BNA) 1461 (Fed.

The Applicants agree with the Office in that the claimed polynucleotides read on polynucleotides that are not specifically described in the instant specification. However, as discussed in the previous paragraph, the law does not require specific disclosure of *every* species encompassed by a claim for the claim to be patentable.

Further, since the instant claims are free of the art, the Applicants respectfully submit that the species to which the Office refer would be later found species encompassed by the instant claims. Since it is well established that explicit description of later-discovered species that now fall within a claimed genus is not required,<sup>6</sup> the Office's reasoning for rejecting these claims appears to be inadequate, according to the current law of written description.

In view of the foregoing, the Applicants respectfully submit that this rejection of the claims should be withdrawn without any further discussion.

**Rejection of claims under 35 U.S.C. § 112, first paragraph (new matter)**

The claims are rejected as containing new matter. Specifically, the Office asserts that the limitation of "50" contiguous nucleotides is not supported in the specification.

The Office asserts that "p30 line 4) has nothing to do with the length of polynucleotides". However, the Applicants respectfully submit that the Office misread the page and line pointed to by Applicants in support of the amendment. As recited in page 4 of the previous response, support for the amendment may be found in "line 30 on page 4" (not "p30 line 4" as the Office reads).

Since it is clearly stated that the claimed polynucleotides may be at least 50 contiguous nucleotides in length in line 30 on page 4 of the instant specification, the Applicants respectfully submit that the claims are fully supported by the instant specification and the rejection may be withdrawn.

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Cir. 1989).

<sup>6</sup> *Rexnord Corporation v. Laitram Corporation*, 274 F.3d 1336, 1344, 60 U.S.P.Q.2d (BNA) 1851, 1856 (Fed. Cir. 2001) ("Our case law is clear that an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention."). See also *In re Hogan and Banks*, 559 F.2d 595, 605-06, 194 U.S.P.Q. (BNA) 527, 537 (C.C.P.A. 1977); *United States Steel Corporation v. Phillips Petroleum Company*, 865 F.2d 1247, 1251-52, 9 U.S.P.Q.2d (BNA) 1461, 1465 (Fed. Cir. 1989).

**CONCLUSION**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number 2300-1624.

Respectfully submitted,  
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